



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

SUBREGULATION 4A.6(3) CERTIFICATE

Instructions for completing a Certificate for subregulation 4A.6(3) of the *Therapeutic Goods (Medical Devices) Regulations 2002*

This certificate must be properly completed as part of the application form approved by the Secretary under subregulation 4A.2(4) of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), for an application for a conformity assessment body determination.

In deciding whether to make a conformity assessment body determination under subregulation 4A.6(1), the Secretary must, under subregulation 4A.6(3) of the MD Regulations, consider whether the Australian corporation that is the applicant for the conformity assessment body determination, or specified persons associated with the corporations, has, within the 10 years immediately before the application, met one of the circumstances listed in subparagraphs 4A.6(3)(a)(iv)-(x) such as, for example, having been convicted of an offence against the *Therapeutic Goods Act 1989* (the Act) or a corresponding State law.

The Act and MD Regulations may be viewed on the Federal Register of Legislation, without charge, at <https://www.legislation.gov.au>.

All applicants for a conformity assessment body determination are expected to self-assess whether they, or certain other persons associated with the applicant, meet the criteria set out below which reflects the criteria set out in paragraph 4A.6(3) of the MD Regulations, and to certify the outcome by submitting this Certificate as part of the application form.

Steps to submitting this certificate

1. Carefully read the relevant provisions of the MD Regulations, and these instructions, and ensure you understand the purpose of this Certificate. Make any enquiries necessary in order to answer the matters set out in this Certificate.
2. Complete the required details, sign and attach any additional information. The signatory must mark the relevant box to either certify (i.e. "I hereby certify that"), or signal their inability to certify (i.e. "I am unable to certify"), when completing the document. Marking both boxes invalidates the certification.
3. To reduce processing times, please send the completed Certificate, with the rest of the application form, by email to AUCAB@health.gov.au.

Note: the signatory must hold a senior position in the Australian corporation (e.g. Chief Executive Officer or Managing Director) and be authorised to make the certification on behalf of the Australian corporation.

Further information

Under regulation 4A.3 of the MD Regulations, the Secretary may, by written notice, require an applicant for a conformity assessment body determination to give the Secretary, further, specified information or documents concerning the application, within the period specified in the notice (which must not be less than 10 working days after the day the notice is given).

Avoiding an invalid certificate

Your Certificate will not be considered to be valid if:

- the Certificate you lodge is incomplete;
- is unclear or ambiguous; and
- has not been signed by the appropriate person (refer to the Note above).

Privacy information

- For general privacy information, go to <https://www.tga.gov.au/privacy>.

Personal information in applications relating to conformity assessment body determination:

- The personal information is used to maintain a record:
 - of conformity assessment body determination applications;
 - to consider applications; and
 - to contact applicants regarding their application.
- Personal information provided in applications may also be used to contact sponsors or manufacturers of medical devices in the Australian Register of Therapeutic Goods (ARTG) where there is a need to do so – for example, in the event of a safety, or performance issue concerning the manufacture of certain goods, or to administer fees and payments.
- Personal information relating to Australian corporations who hold conformity assessment body determination may be disclosed where authorised or required by an Australian law, Court or Tribunal order; or with the consent of the person the information is about.

Note: By way of guidance, the Act defines “major interest holder” in relation to a body corporate as a person who:

- (a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or
- (b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital).

Certificate for subregulation 4A.6(3) of the *Therapeutic Goods (Medical Devices) Regulations 2002*

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hold the position of	2
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at	4

EITHER

hereby certify that, in relation to the application for a conformity assessment body determination,

dated _____ none of the following people:

- i. the applicant for the conformity assessment body determination (the Australian corporation);
- ii. a person (a manager) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Australian corporation's affairs;
- iii. a major interest holder of the Australian corporation;

has, within the 10 years immediately before this application:

- iv. been convicted of an offence against the *Therapeutic Goods Act 1989* (the Act) or a corresponding State law; or
- v. been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
- vi. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of the Act or a corresponding State law; or
- vii. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
- viii. breached a condition of a conformity assessment body determination; or
- ix. had a conformity assessment body determination in respect of the person suspended or revoked; or
- x. been a manager, or a major interest holder, of a body corporate in respect of which subparagraphs (iv), (v), (vi), (vii), (viii) or (ix) applies in that 10 years, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate.

OR

I am **unable** to certify that subparagraphs (iv) - (x) can be met as set out above (please attach supporting information if this option is chosen).

1 Insert full name of individual, or CEO / Managing Director / or equivalent of applicant.

2 Insert position title of applicant

3 Insert applicant name

4 Insert applicant street address

I hereby declare that the above information is true and correct:

Full name (printed)		
Signature		Date

Witness full name		
Witnessed by (Signature)		Date

Note: Giving false or misleading information is a criminal offence under the Criminal Code.